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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,250	10/17/2005	Hiroshi Kase	00005.001217.PC	6976

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FITZPATRICK CELLA HARPER & SCINTO
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NEW YORK, NY 10112

EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT	PAPER NUMBER
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1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/553,250

Applicant(s)

KASE ET AL.

Examiner

Renee Claytor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 7-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2 and 7-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Group I, claim(s) 1-19 and 38, drawn to a method of treating an anxiety disorder.
- II. Group II, claim(s) 20-24, drawn to a method of treating anxiety disorder comprising administration of a xanthine derivative represented by formula (I).
- III. Group III, claim(s) 25-31, drawn to a method of treating an anxiety disorder, comprising administration of at least one adenosine A_{2A} receptor antagonist in combination with an anxiolytic other than the adenosine A_{2A} receptor antagonist.
- IV. Group IV, claim(s) 32-37, drawn to a composition comprising an adenosine A_{2A} receptor antagonist and an anxiolytic other than the adenosine A_{2A} receptor antagonist.

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The method for determining whether the requirement of unity of invention is satisfied is described as follows: unity of inventions exists only when there is a technical relationship among the claimed inventions

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involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art, and therefore constitutes a "special technical feature", should be considered with respect to novelty and inventive step.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: a method for treating an anxiety disorder comprising administration of an adenosine A_{2A} receptor antagonist is disclosed in US Patent 5,047,534 (Col. 2, lines 20-61 and Col. 9, lines 59-60).

As a result, no special technical feature exists among the different groups of inventions because Invention I fails to make a contribution over the prior art due to a corresponding lack of novelty (i.e., the composition of Invention I is already known in, and therefore anticipated by, the prior art). In conclusion, there is a lack of unity of invention, as Inventions I and II do not relate to, and are not so linked as to form, a single general inventive concept.

Invention III is drawn to a method of treating anxiety comprising administration of at least one adenosine A_{2A} receptor antagonist in combination with an anxiolytic other than the adenosine A_{2A} receptor antagonist. US Pg-Pub 2003/0139395 teaches a method of treating anxiety comprising administration of an adenosine A_{2A} receptor antagonist in combination with anxiolytic agents (paragraph 0008). Therefore, US Pg-Pub 2003/0222831 teaches an identical method of treating anxiety with an adenosine

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A_{2A} receptor antagonist in combination with an anxiolytic agent as described in Invention III.

As a result, no special technical feature exists among the different groups of inventions because Invention III fails to make a contribution over the prior art due to a corresponding lack of novelty (i.e., the composition of Invention III is already known in, and therefore anticipated by, the prior art). In conclusion, there is a lack of unity of invention, as Inventions I and III do not relate to, and are not so linked as to form, a single general inventive concept.

Invention IV is drawn to a composition comprising an adenosine A_{2A} receptor antagonist and an anxiolytic other than the adenosine A_{2A} receptor antagonist. US Pg-Pub 2003/0139395 teaches a pharmaceutical composition comprising an adenosine A_{2A} receptor antagonist and an anxiolytic (claim 9). Therefore, US Pg-Pub 2003/0139395 teaches an identical composition with an adenosine A_{2A} receptor antagonist and an anxiolytic as described in Invention IV.

As a result, no special technical feature exists among the different groups of inventions because Invention IV fails to make a contribution over the prior art due to a corresponding lack of novelty (i.e., the composition of Invention III is already known in, and therefore anticipated by, the prior art). In conclusion, there is a lack of unity of invention, as Inventions I and IV do not relate to, and are not so linked as to form, a single general inventive concept.

Specie Election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

adenosine A_{2A} receptor antagonist or xanthine derivative

Applicant is required, in reply to this action, to elect **one** adenosine A_{2A} receptor antagonist to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion to Restriction Requirement

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Due to the complex nature of the instant restriction requirement, a written restriction requirement was necessitated. See MPEP § 812.01.

Contact Information

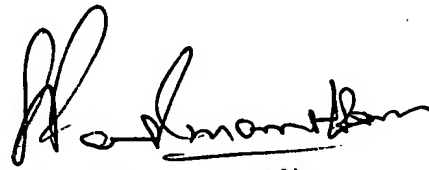
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Renee Claytor



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER